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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,368	12/20/1999	PETER KAMP HANSEN	4324.224-US	2312
25908	7590	11/26/2003	EXAMINER	
NOVOZYMES NORTH AMERICA, INC. 500 FIFTH AVENUE SUITE 1600 NEW YORK, NY 10110				RAO, MANJUNATH N
		ART UNIT		PAPER NUMBER
		1652		

DATE MAILED: 11/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/467,368	HANSEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Manjunath N. Rao, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 September 2003.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 72-90 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 72-90 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
  - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

Claims 72-90 are currently pending and are present for examination.

Applicants' amendments and arguments filed on 9-4-03, have been fully considered and are deemed to be persuasive to overcome the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Specification***

Examiner requests applicant to update the relationship of the instant application with other US application on the first line of the specification.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 72-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lischnig et al. (Biotechnology letters, 1993, Vol. 15(4):411-414) or Gomes et al. (Appl. Microbiol. Biotechnol., 1993, Vol. 39:700-707) and Haarasilta et al. (US 5,314,692, 5-24-1994), Hazlewood et al. (WO 93/25693, 12-23-1993).

Claims 72-90 of the instant application are drawn to an animal feed comprising a xylanase enzyme isolated from *Humicola lanuginosa* (*Syn.*, *Thermomyces lanuginosus*) with

characteristics as disclosed in claim 72 and a method of improving the growth of an animal by feeding said animal feed.

Lischnig et al. or Gomes et al. teach the isolation and characterization of the xylanase enzyme from *Humicola lanuginose*. Applicants also acknowledge (See page 1, line 28-33) such a teaching in the above references. However, the references do not teach the use of said enzyme for supplementing an animal feed or an animal feed comprising said enzyme.

The use of xylanases for supplementation of animal feeds has been known in the art for quite some time. The references of Hazlewood et al. and Haarasilta et al. teach the extensive use of xylanase enzymes in food and feed industry (see the entire reference of Hazlewood et al., specifically pages 20-23). Specifically Hazelwood et al. teach that chicks when fed feeds supplemented with xylanase improve in their weight gain. The reference teaches that the effects of undigested pentosans --which have been implicated for poor nutrient uptake and sticky droppings-- can be overcome by the use of feed supplemented with xylanase.

Therefore combining the teachings of the above references, it would have been obvious to one skilled in the art to use the knowledge existing in the field of enzyme purification, and recombinant techniques at the time the application was filed, to purify the thermostable xylanase taught by Lischnig et al. or Gomes et al. to homogeneity and use it for making an animal feed comprising said enzyme or make recombinant DNA or isolate polynucleotides that hybridize to said recombinant DNA under the highly stringent conditions and isolate the encoded xylanase and use it for making an animal feed as claimed in claims 72-90. While the references may not teach the testing of the enzyme for residual activity at the temperatures claimed in the instant application, they all teach that the enzyme is thermostable. Furthermore, since the enzyme in the

references has been isolated from the very same microorganism as that in the instant application, Examiner takes the position that the enzyme in the reference and the enzyme claimed in the instant application are one and the same and the thermostable characteristics and residual activity characteristics are all inherent features of the enzyme. One of ordinary skill in the art would have been motivated to do so as the xylanases taught in the above references are thermostable and therefore withstand the higher temperatures that may have to be used during the process of making, storing and transporting the feed. One of ordinary skill in the art would have a reasonable expectation of success since the art is rich in teachings regarding use of xylanase enzyme in the field of food and feed industry, and specifically Hazelwood et al. demonstrate such a use. Therefore Lischnig et al. or Gomes et al. in combination with Hazlewood et al. or Haarasilta et al. render claims 72-90 *prima facie* obvious to one of ordinary skill in the art.

[Applicants may argue that claims are drawn to xylanases that are encoded by polynucleotides which hybridize to nucleotides 31-705 of SEQ ID NO:1 and the references provided by the Examiner fails to provide such sequences. Such an argument would not be persuasive to overcome the rejection because, based on the characteristics of the enzyme in the reference and the instant xylanase, Examiner takes the position that the enzyme in the reference and the instant enzyme are one and the same and the amino acid sequences and polynucleotide sequences that encode them are inherent characteristics. Since the Office does not have the facilities for examining and comparing applicants' protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See *In re Best*, 562 F.2d

1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald* et al., 205 USPQ 594. Furthermore, the decisions handed down in *In re Bell* and *In re Deuel* also does not apply to the above situation. This is because applicants are not claiming polynucleotides encoding the xylanase in which case a reference showing the purified protein would not have rendered the DNA obvious (provided applicants had provided a SEQ ID NO for the polynucleotide). However, in the instant case applicants are claiming the a composition comprising the polypeptide and the decisions of *In re Bell* and *In re Deuel* does not apply.]

In response to the previous Office action, applicants have traversed the above rejection basically arguing that none of the cited references teach or suggest the use of thermostable xylanases in animal feed composition or that there would be any advantage to using a thermostable xylanase over a thermolabile xylanase in animal feed. Examiner respectfully disagrees with such an argument. While the references may not explicitly teach the advantages of using a thermostable enzyme over a thermolabile enzyme, such advantages would be readily obvious to those skilled in the art and Examiner has enumerated such advantages in his rejection. Therefore, the teachings by the reference of very same xylanase and the teachings for use of xylanases in general in animal feeds are enough to render the above invention *prima facie* obvious to those skilled in the art.

Applicants next argue against the rejection using the doctrine of “surprising and unexpected results”. Applicants refer to a comparative experiment in which they compare a commercial enzyme with that of the invention and argue that the animal feed comprising the commercial enzyme at a dose of 400 FXU/kg gave a % fat digestion in the range of 72.1-74.3, while the animal feed comprising the present invention gave a % fat digestion in the range of

72.1-74.3 even though the xylanase was dosed at 100 or 200 FXU/kg and therefore the instant invention demonstrated superior property not predicted by prior art and that these results are surprising and unexpected. Examiner finds it difficult to accept the above results as surprising or unexpected. This is because it is not clear as to how a carbohydrase known to act on complex carbohydrates can increase % fat digestion or how the activity of the xylanase contributes towards fat digestion. Next, for sake of argument even if we accept that xylanase affected fat digestion, the results do not appear to be straight forward. For example, as applicants have not determined as to what would have been the %fat digestion values of commercial enzyme at lower doses, it is quite possible that the enzyme concentration of 400 FXU/kg may be a saturating concentration such that increased amounts of the enzyme had no effect on the % fat digestibility.

Examiner has considered the Declaration of Dan Patterson submitted by the applicant under 37 CFR 1.132. The declaration describes the experiments comparing the metabolizing energy available to two groups of test animals, wherein one group was fed an animal feed comprising the invention and the other group was fed an animal feed comprising the control xylanase enzyme isolated from *Aspergillus* and concludes that animal feed comprising the invention results in significantly better feed utilization than animal feed comprising the xylanase from *Aspergillus*. A perusal of the data provided indicates that the metabolizable energy (AME) was 13.65 for feed without any enzyme and 14.50 for feed containing instant enzyme versus 14.15 for feed comprising the control enzyme from *Aspergillus*. Examiner finds it difficult to accept that there is a significant difference between the AME 14.50 versus AME 14.15 for the control enzyme, a difference of 0.35 units, without any statistical analysis of the results. In

view of lack of a showing that a statistically significant difference exists in the results between the feed comprising the instant enzyme and the feed comprising the control enzyme, Examiner has concluded that the results are neither surprising nor unexpected findings. Hence the above rejection is maintained.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 72-90 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,245,546 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to the same xylanase enzyme encoded by the same polynucleotide (nucleotides 31-705 of SEQ ID NO:1) and a premix and a process of making animal feed comprising the above xylanase enzyme.

In response to the above rejection in the previous Office action, applicants have responded that they will submit a Terminal Disclaimer upon the indication of allowable subject matter. Examiner maintains the rejection for reasons of record.

***Conclusion***

None of the claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703)-308-3804. The fax number for Official Papers to Technology Center 1600 is (703)-305-3014.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Manjunath N. Rao  
Patent Examiner, A.U. 1652

*Rebecca E. Prouty*  
**REBECCA E. PROUTY**  
**PRIMARY EXAMINER**  
**GROUP 1800**  
**1652**